



# CBER Critical Path Initiative Workshop 07 October 04

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IMMUNE DEFICIENCY FOUNDATION

# Scientific Opportunities for Facilitating Development of Blood and Blood Products

- Standardized Assays for Therapeutic Antibodies
  - Selection of clinically relevant antibodies
    - Expansion of CFR required tests
    - Consensus development workshop to resolve selections
  - Correlation of Potency with Effectiveness
    - Development of functional assays

# Scientific Opportunities for Facilitating Development of Blood and Blood Products

- Surrogate Markers to license new agents
  - Antibodies with specificity for encapsulated organisms
  - Analysis of sera banks from recent licensure trials

# Scientific Opportunities for Facilitating Development of Blood and Blood Products

- Safety Issues
  - Universal integration of biologically relevant established procedures for plasma derivatives
    - pathogen clearance
    - prion removal/inactivation
  - Role for FDA
    - Scientific evaluation of procedures

# Scientific Opportunities for Facilitating Development of Blood and Blood Products

- Exploration of the role of animal models in facilitating licensure of new products
  - Antibodies that cannot be ethically tested
    - Agents of bioterrorism
    - Emerging Infectious Diseases